DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 25, 2014

Biomet Spine, LLC
Kimberly McCoy, MBA, RAC
Regulatory Affairs Project Manager
310 Interlocken Parkway, Suite 120
Broomfield, Colorado 80021

Re: K141804
Trade/Device Name: Polaris Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ
Dated: June 30, 2014
Received: July 3, 2014

Dear Ms. McCoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141804

Device Name
Polaris Spinal System

Indications for Use *(Describe)*
The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, Scheuermann's disease, and/or lordosis,), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

The Ballista and Cypher MIS instruments are intended to be used with Ballista/ Cypher MIS /Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista/ Cypher MIS instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications.

For pediatric patients, the Polaris Spinal System may be used for posterior, non-cervical pedicle screw fixation as an adjunct to fusion to treat adolescent idiopathic scoliosis and is also indicated for treatment of the following conditions: spondylolisthesis/spondylolysis and fractures caused by tumor and/or trauma. Pedicle screw fixation is limited to a posterior approach.

The Polaris Spinal System may be used with the instruments in the AccuVision Minimally Invasive Spinal Exposure System to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The dominos in the Polaris Spinal System can be used to connect the Polaris Spinal System to the Altius Spinal System, Lineum OCT Spine System, the Array Spinal System, the Biomet Omega21 Spinal System, or the Synergy Spinal System to achieve additional levels of fixation. Please refer to the individual system's Package Insert for a list of the indications for use for each system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BIOMET
SPINE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	June 30, 2014
Applicant/Sponsor:	Biomet Spine, LLC 310 Interlocken Parkway Suite 120 Broomfield, CO 80021
Contact Person:	Kimberly McCoy, MBA, RAC Regulatory Affairs Project Manager Phone: 303-465-8923 Fax: 303-501-8444
Trade name:	Polaris Spinal System
Common Name:	Non-cervical spinal fixation system
Device Class:	Class III
Classification Name (Product Code):	Pedicle screw spinal system (NKB, OSH, MNH, MNI, KWP, KWQ)
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3050, 888.3060 and 888.3070

Device Description:

The Polaris Spinal System is a non-cervical spinal fixation device made from titanium alloy (Ti-6Al-4V) per ASTM F136, unalloyed titanium per ASTM F67, stainless steel per ASTM F138 or ASTM F1314 and Cobalt Chrome Alloy (Co-28Cr-6Mo) per ASTM F1537. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, fixation washers, rod connectors/dominos, various cross connectors and accessories. This submission is to clear modifications to the Polaris Spinal System to include Hydroxyapatite (HA) Coated Screws and a variation in shaft geometry on the multiaxial screws.

Indications for Use:

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e.,

scoliosis, kyphosis, Scheuermann's disease, and/or lordosis,), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

The Ballista and Cypher MIS instruments are intended to be used with Ballista/ Cypher MIS /Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista/ Cypher MIS instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications.

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Summary of Technologies:

The technological characteristics of the subject Polaris Spinal System components remain the same as, or similar to, the predicate devices in regards to intended use, indications for use, design, materials, manufacturing methods, sterility, fundamental technology, and operational principles.

Performance Data:

Mechanical testing was conducted in accordance with FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004. Per the guidance document, the following testing was conducted: static compression bending, static torsion, and dynamic compression bending fatigue per ASTM F1717, Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model. The mechanical testing verifies that the subject components are substantially equivalent to other spinal systems currently on the market for its intended use and has met all mechanical test requirements based on the worst-case construct testing. In addition, the guidance document Information Needed for Hydroxyapatite Coated Orthopedic Implants dated March 10, 1995 was followed for the HA coated screws.

Substantial Equivalence:

The Polaris Screws in the Polaris Spinal System is substantially equivalent to the Polaris Spinal System (K140123, K090203) and the Globus Medical (Globus) Revere Stabilization System (K122226) in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles.

Conclusion:

The Polaris Screw is substantially equivalent to the predicate systems as spinal fixation devices in regards to intended use, indications for use, fundamental technology including design, materials, manufacturing methods, sterility, and operational principles. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Polaris Spinal System, which has been cleared for a non-cervical spinal fixation. Based on this information, the subject modifications do not raise any new issues regarding the safety or efficacy when compared to its predicates.